



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 09/806,125

Filed: 3/28/2001

1st Inventor: MATSUTANI, Eisuya

For: Agent that retards the transformation of hormone-dependent cancer to non-hormone dependent cancer

Atty. Dkt. No. 2556 USOP

Art Unit: 1642

Examiner: Rawlings, S.

Allowed:

Batch:

Paper No.:

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Response to Notice to Comply with Sequence Listing Requirements

BOX SEQ
Commissioner for Patents
Washington, D.C. 20231
Sir:

In response to the Notice to Comply mailed April 7, 2003, Applicants respectfully submit, along with a copy of the Notice, a substitute written Sequence Listing and a replacement DOS Text CRF Sequence Listing file "2556SEQ.txt" on the enclosed 3.5" IBM PC/AT computer disk.

The undersigned hereby certifies that the CRF and the written Sequence Listing are the same in content. The Sequence Listing contains no new matter.

Respectfully submitted,

Dated: April 22, 2003

(847)383-3372

(847)383-3391

Mark Chao, Ph.D., Reg. No. 37,293

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Attorney for Applicants

Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
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Notice to Comply

Application No.

09/806,125

Applicant(s)

MATSUTANI ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

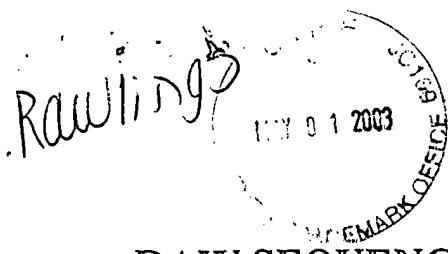
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

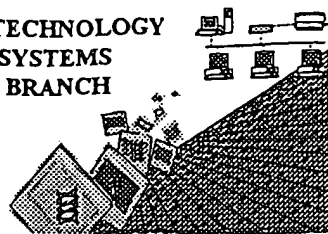
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BIOTECHNOLOGY
SYSTEMS
BRANCH



**RAW SEQUENCE LISTING
ERROR REPORT**

Re-RUN

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/806,125B
Source: 1620
Date Processed by STIC: 3/12/2003

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THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.

PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)

PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER
VERSION 3.1 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND
TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/efb/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. Hand Carry directly to:
U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7th Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202
Or
U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
4. Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

MAI 01 2003

Raw Sequence Listing Error Summary

ERROR DETECTED

SUGGESTED CORRECTION

SERIAL NUMBER: 09/806/125B

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 Wrapped Nucleics
 Wrapped Aminos
The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
- 2 Invalid Line Length
The rules require that a line not exceed 72 characters in length. This includes white spaces.
- 3 Misaligned Amino
 Numbering
The numbering under each 5^o amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
- 4 Non-ASCII
The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
- 5 Variable Length
Sequence(s) contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
- 6 PatentIn 2.0
 "bug"
A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) . Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 7 Skipped Sequences
 (OLD RULES)
Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
(i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)
(xi) SEQUENCE DESCRIPTION: SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
This sequence is intentionally skipped

Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
- 8 Skipped Sequences
 (NEW RULES)
Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence.
<210> sequence id number
<400> sequence id number
000
- 9 Use of n's or Xaa's
 (NEW RULES)
Use of n's and/or Xaa's have been detected in the Sequence Listing.
Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of a or Xaa; and which residue n or Xaa represents.
- 10 Invalid <213>
 Response
Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or Artificial Sequence.
- 11 Use of <220>
Sequence(s) missing the <220> "Feature" and associated numeric identifiers and responses.
Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 06/01/1998, Vol 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
- 12 PatentIn 2.0
 "bug"
Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
- 13 Misuse of n
n can only be used to represent a single nucleotide in a nucleic acid sequence. N is not used to represent any value not specifically a nucleotide.

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1600



RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/806,125B

DATE: 03/12/2003
TIME: 13:55:58

Input Set : A:\2556usop.ST25.txt
Output Set : N:\CRF4\03122003\I806125B.raw

3 <110> APPLICANT: MATSUTANI, Etsuya
4 NAITO, Kenichiro
6 <120> TITLE OF INVENTION: Agents For Retarding Change of Hormone-dependent Cancer into
7 Hormone-independent Cancer
9 <130> FILE REFERENCE: 2556USOP
11 <140> CURRENT APPLICATION NUMBER: 09/806,125B
12 <141> CURRENT FILING DATE: 2001-03-28
14 <150> PRIOR APPLICATION NUMBER: PCT/JP99/05533
15 <151> PRIOR FILING DATE: 1999-10-07
17 <150> PRIOR APPLICATION NUMBER: JP 10-286793
18 <151> PRIOR FILING DATE: 1998-10-08
20 <160> NUMBER OF SEQ ID NOS: 13
22 <170> SOFTWARE: PatentIn version 3.2
24 <210> SEQ ID NO: 1
25 <211> LENGTH: 10
26 <212> TYPE: PRT
27 <213> ORGANISM: artificial
29 <220> FEATURE:
30 <223> OTHER INFORMATION: peptide
33 <220> FEATURE:
34 <221> NAME/KEY: MISC_FEATURE
35 <222> LOCATION: (6)..(6)
36 <223> OTHER INFORMATION: D-Leu
38 <220> FEATURE:
39 <221> NAME/KEY: MISC_FEATURE
40 <222> LOCATION: (10)..(10)
41 <223> OTHER INFORMATION: -NH-C2H5
43 <400> SEQUENCE: 1

W--> 45 Pro His Trp Ser Tyr Xaa Leu Arg Pro Xaa

46 1 5 10

49 <210> SEQ ID NO: 2

50 <211> LENGTH: 10

51 <212> TYPE: PRT

52 <213> ORGANISM: artificial

54 <220> FEATURE:

55 <223> OTHER INFORMATION: peptide

58 <220> FEATURE:

59 <221> NAME/KEY: MISC_FEATURE

60 <222> LOCATION: (6)..(6)

61 <223> OTHER INFORMATION: DLeu, DAla, DTrp, DSer(tBut), D2Nal, DHis(ImBzl)

63 <220> FEATURE:

64 <221> NAME/KEY: MISC_FEATURE

65 <222> LOCATION: (10)..(10)

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pg 1-3, 6

Does Not Comply
Corrected Diskette Needed:

insufficient explanation
give source of genetic material (see item 11 on Euro Summary Sheet)

FYI: Xaa can only represent a single amino acid,
nothing else

RAW SEQUENCE LISTING

DATE: 03/12/2003

PATENT APPLICATION: US/09/806,125B

TIME: 13:55:58

*Xaa can
only represent
a single amino acid*

Input Set : A:\2556usop.ST25.txt

Output Set: N:\CRF4\03122003\I806125B.raw

66 <223> OTHER INFORMATION: NH-C2H5, Gly-NH2 *CK*
 68 <400> SEQUENCE: 2
 W--> 70 Pro His Trp Ser Tyr Xaa Leu Arg Pro Xaa
 71 1 5 10
 74 <210> SEQ ID NO: 3
 75 <211> LENGTH: 11
 76 <212> TYPE: PRT
 77 <213> ORGANISM: artificial
 79 <220> FEATURE:
 80 <223> OTHER INFORMATION: peptide
 83 <220> FEATURE:
 84 <221> NAME/KEY: MISC_FEATURE
 85 <222> LOCATION: (1)..(1)
 86 <223> OTHER INFORMATION: N(4H2-furoyl)Gly, NAc
 88 <220> FEATURE:
 89 <221> NAME/KEY: MISC_FEATURE
 90 <222> LOCATION: (2)..(2)
 91 <223> OTHER INFORMATION: D2Nal
 93 <220> FEATURE:
 94 <221> NAME/KEY: MISC_FEATURE
 95 <222> LOCATION: (3)..(3)
 96 <223> OTHER INFORMATION: D4ClPhe
 98 <220> FEATURE:
 99 <221> NAME/KEY: MISC_FEATURE
 100 <222> LOCATION: (4)..(4)
 101 <223> OTHER INFORMATION: D3Pal
 103 <220> FEATURE:
 104 <221> NAME/KEY: MISC_FEATURE
 105 <222> LOCATION: (6)..(6)
 106 <223> OTHER INFORMATION: NMeTyr, Tyr, Aph(Atz), NMeAph(Atz)
 108 <220> FEATURE:
 109 <221> NAME/KEY: MISC_FEATURE
 110 <222> LOCATION: (7)..(7)
 111 <223> OTHER INFORMATION: DLys(Nisp), DCit, DLys(AzaglyNic), DLys(AzaglyFur), DhArg
 (Atz),
 112 DhCi
 114 <220> FEATURE:
 115 <221> NAME/KEY: MISC_FEATURE
 116 <222> LOCATION: (9)..(9)
 117 <223> OTHER INFORMATION: Lys(Nisp), Arg, hArg(Et2)
 119 <220> FEATURE:
 120 <221> NAME/KEY: MISC_FEATURE
 121 <222> LOCATION: (11)..(11)
 122 <223> OTHER INFORMATION: Dala
 124 <400> SEQUENCE: 3
 W--> 126 Xaa Xaa Xaa Xaa Ser Xaa Xaa Leu Xaa Pro Xaa
 127 1 5 10
 130 <210> SEQ ID NO: 4
 131 <211> LENGTH: 6
 132 <212> TYPE: PRT

RAW SEQUENCE LISTING
 PATENT APPLICATION: US/09/806,125B

DATE: 03/12/2003
 TIME: 13:55:58

Input Set : A:\2556usop.ST25.txt
 Output Set: N:\CRF4\03122003\I806125B.raw

133 <213> ORGANISM: artificial
 135 <220> FEATURE:
 136 <223> OTHER INFORMATION: peptide
 138 <400> SEQUENCE: 4
 140 His Arg Asp Leu Ala Ala
 141 1 5
 144 <210> SEQ ID NO: 5
 145 <211> LENGTH: 5
 146 <212> TYPE: PRT
 147 <213> ORGANISM: artificial
 149 <220> FEATURE:
 150 <223> OTHER INFORMATION: peptide
 152 <400> SEQUENCE: 5
 154 Ser Asp Val Trp Ser
 155 1 5
 158 <210> SEQ ID NO: 6
 159 <211> LENGTH: 16
 160 <212> TYPE: DNA
 161 <213> ORGANISM: artificial
 163 <220> FEATURE:
 164 <223> OTHER INFORMATION: primer
 167 <220> FEATURE:
 168 <221> NAME/KEY: misc_feature
 169 <222> LOCATION: (3)..(3)
 170 <223> OTHER INFORMATION: C or T
 172 <220> FEATURE:
 173 <221> NAME/KEY: misc_feature
 174 <222> LOCATION: (4)..(4)
 175 <223> OTHER INFORMATION: C or A
 177 <220> FEATURE:
 178 <221> NAME/KEY: misc_feature
 179 <222> LOCATION: (9)..(10)
 180 <223> OTHER INFORMATION: C or T
 182 <400> SEQUENCE: 6
 W--> 183 canngggann ggcbgc
 186 <210> SEQ ID NO: 7
 187 <211> LENGTH: 16
 188 <212> TYPE: DNA
 189 <213> ORGANISM: artificial
 191 <220> FEATURE:
 192 <223> OTHER INFORMATION: primer
 195 <220> FEATURE:
 196 <221> NAME/KEY: misc_feature
 197 <222> LOCATION: (2)..(2)
 198 <223> OTHER INFORMATION: a or g
 200 <220> FEATURE:
 201 <221> NAME/KEY: misc_feature
 202 <222> LOCATION: (8)..(8)
 203 <223> OTHER INFORMATION: c or a

16

RAW SEQUENCE LISTING

DATE: 03/12/2003

PATENT APPLICATION: US/09/806,125B

TIME: 13:55:58

Input Set : A:\2556usop.ST25.txt

Output Set: N:\CRF4\03122003\I806125B.raw

205 <220> FEATURE:
 206 <221> NAME/KEY: misc_feature
 207 <222> LOCATION: (11)..(11)
 208 <223> OTHER INFORMATION: g or a
 210 <220> FEATURE:
 211 <221> NAME/KEY: misc_feature
 212 <222> LOCATION: (14)..(14)
 213 <223> OTHER INFORMATION: a or g
 215 <400> SEQUENCE: 7

W--> 216 anctccanac ntcnct

16

219 <210> SEQ ID NO: 8
 220 <211> LENGTH: 17
 221 <212> TYPE: DNA
 222 <213> ORGANISM: artificial
 224 <220> FEATURE:
 225 <223> OTHER INFORMATION: primer
 228 <220> FEATURE:
 229 <221> NAME/KEY: misc_feature
 230 <222> LOCATION: (3)..(3)
 231 <223> OTHER INFORMATION: c or t
 233 <220> FEATURE:
 234 <221> NAME/KEY: misc_feature
 235 <222> LOCATION: (4)..(4)
 236 <223> OTHER INFORMATION: c or a
 238 <220> FEATURE:
 239 <221> NAME/KEY: misc_feature
 240 <222> LOCATION: (6)..(6)
 241 <223> OTHER INFORMATION: g or a
 243 <220> FEATURE:
 244 <221> NAME/KEY: misc_feature
 245 <222> LOCATION: (10)..(10)
 246 <223> OTHER INFORMATION: c or t
 248 <220> FEATURE:
 249 <221> NAME/KEY: misc_feature
 250 <222> LOCATION: (12)..(12)
 251 <223> OTHER INFORMATION: g or t
 253 <220> FEATURE:
 254 <221> NAME/KEY: misc_feature
 255 <222> LOCATION: (15)..(15)
 256 <223> OTHER INFORMATION: a or t
 258 <400> SEQUENCE: 8

W--> 259 canngngacn tngcngc

17

262 <210> SEQ ID NO: 9
 263 <211> LENGTH: 16
 264 <212> TYPE: DNA
 265 <213> ORGANISM: artificial
 267 <220> FEATURE:
 268 <223> OTHER INFORMATION: primer
 271 <220> FEATURE:

RAW SEQUENCE LISTING

DATE: 03/12/2003

PATENT APPLICATION: US/09/806,125B

TIME: 13:55:58

Input Set : A:\2556usop.ST25.txt

Output Set: N:\CRF4\03122003\I806125B.raw

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272 <221> NAME/KEY: misc_feature
273 <222> LOCATION: (2)..(2)
274 <223> OTHER INFORMATION: a or g
276 <220> FEATURE:
277 <221> NAME/KEY: misc_feature
278 <222> LOCATION: (8)..(8)
279 <223> OTHER INFORMATION: a or c
281 <220> FEATURE:
282 <221> NAME/KEY: misc_feature
283 <222> LOCATION: (14)..(14)
284 <223> OTHER INFORMATION: a or c
286 <400> SEQUENCE: 9
W--> 287 anctccanac gtcnaga 16
290 <210> SEQ ID NO: 10
291 <211> LENGTH: 17
292 <212> TYPE: DNA
293 <213> ORGANISM: artificial
295 <220> FEATURE:
296 <223> OTHER INFORMATION: primer
299 <220> FEATURE:
300 <221> NAME/KEY: misc_feature
301 <222> LOCATION: (3)..(3)
302 <223> OTHER INFORMATION: c or t
304 <220> FEATURE:
305 <221> NAME/KEY: misc_feature
306 <222> LOCATION: (4)..(4)
307 <223> OTHER INFORMATION: c or a
309 <220> FEATURE:
310 <221> NAME/KEY: misc_feature
311 <222> LOCATION: (6)..(6)
312 <223> OTHER INFORMATION: g or a
314 <220> FEATURE:
315 <221> NAME/KEY: misc_feature
316 <222> LOCATION: (10)..(10)
317 <223> OTHER INFORMATION: c or t
319 <220> FEATURE:
320 <221> NAME/KEY: misc_feature
321 <222> LOCATION: (15)..(15)
322 <223> OTHER INFORMATION: a or g
324 <400> SEQUENCE: 10
W--> 325 canngngacn tggcngc 17
328 <210> SEQ ID NO: 11
329 <211> LENGTH: 16
330 <212> TYPE: DNA
331 <213> ORGANISM: artificial
333 <220> FEATURE:
334 <223> OTHER INFORMATION: primer
337 <220> FEATURE:
338 <221> NAME/KEY: misc_feature

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RAW SEQUENCE LISTING ERROR SUMMARY
 PATENT APPLICATION: US/09/806,125B

DATE: 03/12/2003

TIME: 13:55:59

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 CRF4

Input Set : A:\2556usop.ST25.txt

Output Set: N:\CRF4\03122003\I806125B.raw

Please Note:

Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa.

Seq#:1; Xaa Pos. 6,10
 Seq#:2; Xaa Pos. 6,16
 Seq#:3; Xaa Pos. 1,2,3,4,6,7,9,11/
 Seq#:6; N Pos. 3,4,9,10
 Seq#:7; N Pos. 8,11,14
 Seq#:8; N Pos. 3,4,6,10,12,15
 Seq#:9; N Pos. 2,8,14
 Seq#:10; N Pos. 3,4,6,10,15
 Seq#:11; N Pos. 2,8,11,14

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Invalid <213> Response:

Use of "Artificial" only as "<213> Organism" response is incomplete, per 1.823(b) of New Sequence Rules. Valid response is Artificial Sequence.

Seq#:1,2,3,4,5,6,7,8,9,10,11,12,13